

PUBLIC HEALTH DEPARTMENT[641]

Adopted and Filed

Rule making related to radiation, X-ray equipment, and continuing education

The Public Health Department hereby amends Chapter 41, “Safety Requirements for the Use of Radiation Machines and Certain Uses of Radioactive Materials,” and Chapter 42, “Permit to Operate Ionizing Radiation Producing Machines or Administer Radioactive Materials,” Iowa Administrative Code.

Legal Authority for Rule Making

This rule making is adopted under the authority provided in Iowa Code section 136C.3.

State or Federal Law Implemented

This rule making implements, in whole or in part, Iowa Code chapter 136C.

Purpose and Summary

These amendments provide clarity and updates regarding issues that have evolved over the years that these rules have been in place. The amendments are largely already in practical use in the industry, and the amendments clarify within the rules the activities that are actually occurring or need to be changed to support a need in the industry as a result of the addition of training/testing options from the Department, changes in applied uses for dual X-ray energy absorptiometry (DEXA) machines, and advancements in equipment and the scientific understanding of radiation protection for imaging the abdominal and pelvic area.

Specifically, the amendments do the following:

1. Radiation machines. In numbered paragraph 41.1(3)“a”(3)“5” and subparagraph 41.1(3)“a”(6), the amendments remove a specific reference to the type and place of gonadal shielding to be used and replace it with more general radiation protection and shielding requirements based on diagnostic and clinical needs. This change is being made to align with national consensus that demonstrates a need to change how gonadal shielding is applied due to new understanding of dose weighting factors for tissue and organs, as well as advances in radiation-emitting equipment and detector technologies.

2. Radiation machines. Paragraph 41.1(5)“n” indicates that the use of fluoroscopy by radiologist assistants shall be defined in rule 641—42.6(136C). This is an incorrect reference to Chapter 42. The addition of “radiologist assistant” to the list authorized to supervise fluoroscopy will define this use and align with clinical practice.

3. Permit. In rules 641—42.2(136C) and 641—42.10(136C), the amendments change the name of the X-ray equipment operator permit from bone densitometry to DEXA. Bone densitometry has always been performed using DEXA machines, but recent developments in clinical practice and technology have allowed these machines to expand in use to other body measurements beyond just bone density. These amendments are necessary to more accurately describe the activities performed using the DEXA equipment, which includes both bone densitometry measurements and body composition. To support this change, a definition is added for “body composition” and terminology is changed as appropriate throughout the chapter.

4. Permit. Disciplinary action added for examination subversion. This amendment is needed now that courses and examinations are offered directly by the Department, effective August 2019. Referenced national board standards from the American Registry of Radiologic Technologists (ARRT) certification board are to remain consistent with this definition and assessment of subversion.

5. Permit. Rule 641—42.26(136C), regarding Iowa approval for continuing education (CE), is rescinded since the Department no longer does those approvals. The rules were changed in March 2013

to remove this practice of Iowa approval of CEs, and the rule language allowed for transition at that time. All CE providers have transitioned to the non-Iowa approval processes, so this coverage language is no longer needed.

Public Comment and Changes to Rule Making

Notice of Intended Action for this rule making was published in the Iowa Administrative Bulletin on March 24, 2021, as **ARC 5520C**.

Five public comments were received, all of which recommended that numbered paragraph 41.1(3)“a”(3)“5” and subparagraph 41.1(3)“a”(6) not be amended. The basis for these comments stated that these amendments would remove the requirement to provide radiation protection to the patient through shielding. This is not an accurate interpretation of these amendments. The amendments remove the very specific requirement of gonadal shielding for all imaging examinations, which can cause an increase in radiation dose based on the new considerations of tissue weighting factors and digital technology advancements in radiologic imaging. The rules instead require facilities to establish procedures by which the proper use of radiation protection options, to include shielding, is considered and implemented for each imaging examination. The comments did not provide any scientific evidence contrary to the evidence and statement from the National Council on Radiation Protection that was used as the basis for these amendments.

No changes from the Notice have been made.

Adoption of Rule Making

This rule making was adopted by the State Board of Health on May 12, 2021.

Fiscal Impact

This rule making has no fiscal impact to the State of Iowa.

Jobs Impact

After analysis and review of this rule making, no impact on jobs has been found.

Waivers

Any person who believes that the application of the discretionary provisions of this rule making would result in hardship or injustice to that person may petition the Department for a waiver of the discretionary provisions, if any, pursuant to the Department’s waiver provisions contained in 641—Chapter 178.

Review by Administrative Rules Review Committee

The Administrative Rules Review Committee, a bipartisan legislative committee which oversees rule making by executive branch agencies, may, on its own motion or on written request by any individual or group, review this rule making at its [regular monthly meeting](#) or at a special meeting. The Committee’s meetings are open to the public, and interested persons may be heard as provided in Iowa Code section 17A.8(6).

Effective Date

This rule making will become effective on July 21, 2021.

The following rule-making actions are adopted:

ITEM 1. Amend subparagraph **41.1(3)“a”(3)** as follows:

(3) A chart shall be provided in the vicinity of the diagnostic X-ray system’s control panel which specifies, for all examinations performed with that system, the appropriate technique and guidance for employing available dose reduction methods and technologies across all patient sizes and clinical indications. The following information shall be included:

1. Patient's body part and anatomical size, or body part thickness, or age (for pediatrics), versus technique factors to be utilized unless automatically set by the X-ray system;
2. Type and size of the film or film-screen combination to be used;
3. Type and focal distance of the grid to be used, if any; and
4. Source to image receptor distance to be used, except for dental intraoral radiography; and
5. ~~Type and location of placement of human patient shielding to be used (e.g., gonad).~~

ITEM 2. Amend subparagraph **41.1(3)“a”(6)** as follows:

(6) ~~Gonad shielding of not less than 0.50 millimeter lead equivalent shall be used for human patients, who have not passed the reproductive age, during radiographic procedures in which the gonads are in the useful beam, except for cases in which this would interfere with the diagnostic procedure. A sufficient number of protective apparel (e.g., aprons, gloves, collars) and shields shall be available to provide the necessary radiation protection for all patients and personnel who are involved with X-ray operations.~~

ITEM 3. Amend paragraph **41.1(5)“n”** as follows:

n. Supervision of fluoroscopy. The use of fluoroscopy by radiologic technologists and radiologic students shall be performed under the direct supervision of a licensed practitioner, a radiologist assistant or an advanced registered nurse practitioner (ARNP), pursuant to 655—subrule 7.2(2), for the purpose of localization to obtain images for diagnostic or therapeutic purposes. ~~The use of fluoroscopy by radiologist assistants shall be as defined in 641—42.6(136C).~~

ITEM 4. Adopt the following **new** definition of “Body composition scan” in rule **641—42.2(136C)**:

“*Body composition scan*” means the use of a low dose X-ray to generate images of a color-coded body map.

ITEM 5. Amend rule 641—42.10(136C), introductory paragraph, as follows:

641—42.10(136C) Permit to practice as an X-ray equipment operator in either podiatric radiography or bone densitometry (dual energy X-ray absorptiometry). After January 1, 2015, all individuals performing only bone densitometry or other examinations using DEXA machines must hold a bone densitometry permit.

ITEM 6. Amend paragraph **42.10(1)“e”** as follows:

e. Submit proof of at least a 70 percent score on a department-approved examination.

~~(1) All podiatric X-ray equipment operators must pass the examination with a 70 percent score. After January 1, 2015, all bone densitometry equipment operators must submit proof of at least a 70 percent score on a department-approved examination.~~

~~(2) (1)~~ Three failed attempts on the examination in 42.10(1)“*e*”(1) 42.10(1)“*e*” will require the individual to repeat the formal education or complete a department-approved review program.

~~(3) (2)~~ Each individual making application to take an examination as an X-ray equipment operator to meet the requirements of 42.10“*e*”(1) 42.10(1)“*e*” must submit an application and nonrefundable fee of \$100 to the department each time the individual takes the examination.

ITEM 7. Adopt the following **new** subrule 42.13(5):

42.13(5) An individual reinstating an expired permit shall submit the following:

a. Application to reinstate and a nonrefundable \$150 application fee. If the permit is expired six months or more, all previous exemptions from this chapter are no longer valid and the individual is subject to all requirements of subrule 42.7(1).

b. Any continuing education hours due at time of renewal. If the permit is expired more than one year past the expiration date, 24.0 hours of continuing education obtained within the previous 24 months must be submitted. If the permit includes the radiologist assistant classification, then the individual must submit a total of 50.0 hours of continuing education obtained within the biennium indicated on the individual's permit.

c. Proof that all stipulations of any order(s) of disciplinary or enforcement action have been satisfied.

ITEM 8. Amend rule 641—42.22(136C), catchwords, as follows:

641—42.22(136C) Rules of conduct, self-reporting requirements, and enforcement actions for all permit holders or applicants.

ITEM 9. Amend paragraph **42.22(1)“n”** as follows:

n. Employing fraud or deceit to obtain, attempt to obtain or renew a permit under this chapter or in connection with a certification or license issued from a certifying or licensing entity. This includes altering documents, failing to provide complete and accurate responses or information, ~~or~~ indicating falsely in writing that a permit is valid when that is not the case, or any form of examination subversion.

ITEM 10. Adopt the following **new** paragraph **42.22(2)“c”**:

c. Report potential ethics violations (including state licensing issues and criminal charges and convictions) within 30 days of the occurrence or during the permit holder’s annual renewal process, whichever comes first.

ITEM 11. Rescind **641—Chapter 42, division heading** preceding rule 641—42.26(136C).

ITEM 12. Rescind and reserve rule **641—42.26(136C)**.

ITEM 13. Amend subparagraph **42.31(2)“e”(1)** as follows:

(1) All competency testing for limited radiography shall be directly supervised by the principal or clinical instructor, can only begin after the classroom hours in a category have been completed, and cannot begin until after the clinical site has been approved by the department using the Initial Clinical Site Form.

[Filed 5/13/21, effective 7/21/21]

[Published 6/16/21]

EDITOR’S NOTE: For replacement pages for IAC, see IAC Supplement 6/16/21.